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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/443,986	11/19/1999	DANIEL JOSEPH OMAHONY	99.1064.US	8043

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MARY L SEVERSON PH.D. ESQ
ELAN PHARMACEUTICAL RESEACH CORP
1300 GOULD DRIVE
GAINESVILLE, GA 30504

EXAMINER
ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 01/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/443,986	Applicant(s) OMAHONY, DANIEL JOSEPH	
	Examiner Hope A. Robinson	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *18-26,28,29 and 35-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-17,27,30-34 and 40-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election without traverse of Group I (Claims 1-17, 27, 30-34 and 40-43) in Paper No. 4 is acknowledged.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims are 1-17, 27, 30-34 and 40-43 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the retro-inverted peptide and the specific sequences (SEQ ID NOs: 1-3), does not reasonably provide enablement for derivatives or fragments thereof or a binding portion thereof or a composition for treatment of any mammalian disease or disorder.

The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy

the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to:

I. Quantity of Experimentation Necessary:

The claimed invention is directed to a retro-inverted peptide or a derivative/fragment thereof. In addition, the peptide comprises the amino acid sequences set forth in SEQ ID NOs: 1-3 or a binding portion thereof. Further, the invention is directed to a composition comprising the peptide and the active agent is of value in the treatment of a mammalian disease or disorder. The claims do not recite the specific disease or disorder and the specification does not demonstrate the claimed composition in a medicament to treat any disease or disorder. Moreover, neither the claims nor the specification provides any showing of the claimed derivatives/fragments in association with the claimed invention. Page 5 of the specification provides a discussion as to what is considered to be a derivative. However, there is no showing of any biological activity for the claimed derivative, no sequence identifiers or any special characteristics described. Moreover, the specification provides no description of the claimed fragment or any special features to enable one skilled in the art to be able to practice the full scope of the claimed invention. Therefore, the present application lacks sufficient guidance as to the claimed invention. Further, the specification does not provide any exemplification of the claimed invention with the unspecified amount of derivatives/fragments or a medicament to treat any or all diseases/disorders.

Therefore, the claimed invention does not enable one skilled in the art to be able to make and use the invention without undue experimentation.

II. Amount of direction or guidance presented:

The specification does not provide adequate guidance to be able to practice the claimed invention commensurate in scope with the claims. To examine every derivative/fragment to determine function/biological activity would require undue experimentation. In addition, there is no indicia as to what part of the claimed sequence is considered to be a "binding portion". Furthermore, no guidance is provided as to what disease or disorder the peptide/derivatives/fragments will be used to treat.

III. Presence or absence of working examples:

No working examples are provided *per se*. The specification discusses an animal study involving the bioavailability of insulin. It is difficult to ascertain the nature of the claimed invention from this one record and there is no demonstration of the claimed composition in a therapy or the peptide derivatives/fragments.

IV. Nature of the Invention:

The nature of the invention is a retro-inverted peptide or derivative that specifically binds to gastro-intestinal tract receptor (see for example claim 1). However, the specification does not

provide sufficient guidance/direction to enable the full scope of the claimed invention as the claimed derivative/fragment is not described by size, length or function.

V. State of the prior art and Relative skill of those in the art:

It is disclosed in the specification on page 3 that the applicants have found retro-inverted forms of the GIT targeting agents specific receptor sites in vivo and/or promote uptake of active agents and/or enhance active agent delivery across the GIT into the systemic circulation. The claims are directed to derivatives of the peptide and binding portions of the peptides and no characteristics or attributes of these have been described. As the prior art is silent on the claimed sequences a high level of skill was required at the time the application was filed.

VI. Predictability or unpredictability of the art:

Since very little is known in the prior art about the nature of the invention renders the art unpredictable. The specification should then give more details as to how to make and use the invention in order to be enabling.

VII. Breadth of the claims:

The breadth of the claims are very broad and encompass any disease/disorder and any derivative/fragment or portion thereof of the claimed sequences.

Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-17, 27, 30-34 and 40-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and the dependent claims hereto are indefinite because the recitation of " HPT1, hPEPT1, D2H and hSI" is insufficient to convey what applicant intends to be the claimed invention without the spelled out meaning appearing following the acronym. Note that what the retro-inverted peptide or derivative binds does not define the structure or properties of the peptide *per se*.

Claims 1-17, 27, 30-34 and 40-43 are indefinite as to whether the peptide is isolated. It is noted that the specification describes the peptide as being synthetic, however, as recited in the claims the peptide appears to be naturally occurring. It is suggested that the qualifier synthetic or isolated be recited in association with the peptide.

Claims 2 and 13 is indefinite for the recitation of " binding portion thereof" as it is unclear what portion of the sequences is the "binding portion".

Claims 4-7 lacks antecedent basis as claim 1 does not recite a sequence. It is suggested that the claim 1 is amended to recite the specific sequences.

Claim 8 is indefinite as to the recitation of "bound to a material" as it is unclear what material is referred to in the claim (see also claims 12 and 13).

Claims 8 and 13 are indefinite as the claims recite "treatment of a mammalian disease or disorder" and no specific disease or disorder is identified.

Claim 16 is indefinite because it is unclear how the composition "facilitates" the transport of the active agent.

Claim 30 lacks antecedent basis as the claim refers to "one or more functional activities of said peptide" and claim 1 only refers to one activity of the peptide.

Art of *Record*

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Alvarez et al. (WO 98/51325, November 19, 1998). Alvarez teach peptides capable of facilitating transport of an active agent through a human or animal gastro-intestinal tissue. The

teachings of this reference has not been relied upon as the publication date is the same as applicant's priority document.

Conclusion

5. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday and Wednesday- Friday from 9:00 A.M. to 5:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MS

Patent Examiner

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600